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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/734,012	<b>Applicant(s)</b> PENDRI ET AL.	
	<b>Examiner</b> Mark L. Berch	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-74 is/are pending in the application.  
     4a) Of the above claim(s) 23-40 and 59-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 41-49 and 51-58 is/are rejected.
- 7) ☒ Claim(s) 50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/10/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-22, 41-58, drawn to Synthesis of entecavir via reduction of carboxylic acid esters and intermediates, classified in class 544; 548, subclass 229, 276; 215.
- II. Claims 23-24, drawn to purification, classified in class 544, subclass 276.
- III. Claim 25-40, drawn to Preparation of silyl cyclohexenes and intermediates, classified in class 556, subclass 436, 441, 473, 413, 443.
- IV. Claims 59, 70, drawn to Process of using fused oxazolones and intermediate therefore, classified in class 544; 556, subclass 276; 465.
- V. Claims 60, 72, drawn to Non-epoxy process with cyclopentanones and intermediate therefore, classified in class 544; 556, subclass 276; 482.
- VI. Claims 61, 73, drawn to processes using halocyclopentenenes and intermediate therefore, classified in class 544; 556, subclass 276; 482.
- VII. Claims 62-63, 74, drawn to Processes using lactones and intermediate therefore, classified in class 544; 556, subclass 276; 482.
- VIII. Claim 64, drawn to Processes using dithianes, classified in class 544, subclass 276.
- IX. Claim 65, drawn to non-silicon-using process, classified in class 544, subclass 276.
- X. Claims 66-67, drawn to enzyme-using process to prepare compound 7, classified in class 562, subclass 126.

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XI. Claim 68-69, drawn to Non-enzyme process for producing compound 7, classified in class 562, subclass 126.

XII. Claim 71, drawn to hydroxymethyl, benzyloxymethyl intermediate, classified in class 556; 568, subclass 489; 660.

The inventions are distinct, each from the other because of the following reasons:

The processes (and its therefore) are clearly different because of the distinctive features of each. Group I involves the reduction of a cyclopentene carboxylic acid ester. Group III has the Preparation of silyl cyclohexenes employing a fused cyclobutanone (compound 63). Group IV employs the fused oxazolone 67. Group VIII employs the dithiane 87. Group XII is drawn to intermediates which are not recited in other claimed processes. Group IX is distinctive in that it does not employ silicon intermediates at all. Group VII uses the lactones 49, 50 and 52, not seen in other processes, and Group VI uses the halocyclopentene 40, a type of compound not seen in other processes.

Group II is clearly distinct on account of its being a physical rather than a chemical process. Owing to the broad scope of "intermediates" it covers compounds not mentioned in any other claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for e.g. Group XII is not required for e.g. Group I, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Mr. Henry Gu on 1/11/2005 a provisional election was made traverse to prosecute the invention of Group I, claims 1-22, 41-58. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-40, 59-74 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 41-49, 51-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The meanings quoted by applicants are not the usual meaning at all. Alkyl is a group of the formula  $-C_nH_{2n+1}$ , as is set forth in such sources as Hack's Chemical Dictionary and Hawley's Condensed Chemical Dictionary, or any textbook of organic chemistry. As such it cannot have substituents (unless those substituents themselves meet that definition of alkyl). It is suggested

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that the text in the paragraph bridging pages 4-5 of the specification be amended to state that the alkyl can optionally be substituted with these substituents, so that it is clear that such groups are substituted alkyl. A similar problem occurs for allyl, aryl, benzyl, etc. Thus, for example, the group  $-C(O)Phenyl$  meets the definition of benzyl as given in the specification, but in reality, this is not benzyl but a substituted benzyl.

2. The abbreviation "Bn" needs to be defined.
3. Likewise "MOP" in claim 6, and KHMDS in claim 9, the last 3 terms in claim 15, BHT in claim 16, TFA in claim 17, .
4. "Converting" is indefinite and unduly functional. It simply identifies what is the starting material and what is the final product, without reciting an actual specific step which is performed. As an example, in claim 1, compound 73 is converted into 71, which involves changes at three places. Applicants must use specific terms, such as hydrolysis, which state what actually occurs.
5. What does "protodesilylation" mean in claim 4? Likewise the "protodesilylating" of claim 20, step (g). The examiner cannot locate a definition in standard dictionaries. Applicants are asked to provide a definition which clearly conveys its scope. Note that the term appears with a different spelling in e.g. claims 17-19.
6. In claim 58, what is a "weak acid"? The term "weak acid" is vague. Where is the line between acids which are of weak strength and those of moderate or strong strength. The specification provides no guidance. Terms of degree, are indefinite when the specification contains no "explicit guidelines" to distinguish from things which are not so, *Ex parte Oetiker*, 23 USPQ2d 1651, 1655 (1990) and *Ex parte Oetiker*, 23

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USPQ2d 1641, and *Seattle Box Co. v. Industrial Crating & Packaging, Inc.* 221

USPQ 568, 574. This is not a term which has a fixed meaning.

7. Claim 11 lacks its final period.

Claim 50 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. ~~Status information for~~ published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch  
Primary Examiner  
Art Unit 1624